REMARKS

Applicant wishes to thank the Examiner for the time taken to discuss the examination of this application during the recent telephone conference. As was made clear during the telephone conference, one issue of concern to the Examiner was the lack of an example that showed the use of an exothermic control agent. With an example lacking, the Examiner considered that the claims were made obvious. The Examiner did acknowledge that the specification does disclose that an exothermic control agent may be used with the one or more dipercarboxylic acids.

Applicant respectfully asserts that the claimed invention of the pending patent application is not merely one or more dipercarboxylic acids, because the claimed dipercarboxylic acids are not new. Rather, Applicant claims a composition comprising one or more dipercarboxylic acids, an exothermic control agent and further, a composition that is substantially free of any other organic compounds, thereby providing a composition that may be safely and effectively used in the field, outside of a laboratory, to provide an aqueous sterilizing solution.

The courts have made clear that the rule that no product patent may issue for discovery of a new use for an old product is tempered by the doctrine of slight changes. As stated in *Caterpillar Tractor Co. v. Berco, S.P.A.*, 215 USPQ 948, 959 (D. Wyo. 1982), *aff'd on other grounds*, 714 F.2d 1110 (Fed. Cir, 1983), "even small differences in art may establish patentability where the difference is distinctive, has great utility, and is not obvious." In the case In re Wiggins, 397 F.2d 356 (CCPA 1966), the Court found that adding a known, old composition to a solvent to make a pharmaceutical preparation containing the old composition was a sufficient slight change to make the new compound, comprising the old compound and a solvent in a given concentration, patentable.

This same legal concept was supported in a recent case. Noting that claiming a metabolite of a known drug is not possible because the metabolite is a known compound and therefore, is anticipated, the Federal Circuit stated in *Schering Corp. v. Geneva Pharmaceuticals, Inc.*, 339 F.3d 1373 (Fed. Cir. 2003), "A skilled patent drafter, however, might fashion a claim to cover the metabolite in a way that avoids anticipation. For example, the metabolite may be claimed . . . as a pharmaceutical composition (e.g., with a pharmaceutically acceptable carrier)." *Id.* at 1381.

Applicant has claimed the composition of one or more diperacids with an exothermic control agent as well as other limitations, such as being substantially free from other organic compounds and

wherein the composition is solid particles. Such claiming is what the Federal Circuit was suggesting- that claims may be formulated that provide additional limitations above just the known compound – and that such limitations make the new compound patentable.

The Examples provided within the specification are all addressed to the efficacy of the diperacids in an aqueous solution as a sterilizing agent. They are silent as to how the solutions were made because the effect of the diperacids is what the examples are showing – not how the solutions were made. It is enough that the specification be made enabling of the claimed invention – and the specification states that the exothermic control agent may be added to the composition. Original claim 43, which depended from claim 26, claimed the limitation of adding an exothermic control agent to the compound. Applicant has merely amended independent claim 26 to include the limitation of original claim 43 and then cancelled original claim 43.

Applicant respectfully asserts that as long as the specification is enabling and includes a written description of the claimed invention as well as the best mode, an example of the claimed invention need not be presented to make the claim non-obvious.

Claims 26-37, 40-42 and 44-49 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,503,765 (Schepers, *et al.*) and U.S. Patent No. 5,268,003 (Coope, *et al.*).

Schepers discloses a non-aqueous liquid composition of dipercarboxylic acids that have low solubility in the non-aqueous liquid. The dipercarboxylic acids disclosed by Schepers are mono- or di-percarboxylic amido or imido acids. (Schepers, col. 8, ln. 43-45). These compounds are high molecular weight compounds and Schepers does not disclose their solubility in water. However, because of their high molecular weight, these compounds disclosed by Schepers would not be considered to be soluble in water at concentrations high enough to form a sterilizing solution. This is confirmed by Coope, the secondary reference, saying that "detergent formulations containing a peroxyacid bleach system ... will usually also contain surfactants ... [that] function as a structuring system to suspend the water-insoluble amido peroxyacids in water or any other solvent carrier." (Coope, col. 5, ln., 44-50).

Applicant believes that the Examiner has cited *In re Thuau*, 57 USPQ 324 for the law that a new use for an old composition does not render the old composition patentable. Applicant agrees.

However, Applicant asserts that certain limitations in the pending claims make the claims

distinguishable over the cited references by much more than a mere statement of the intended use of an old composition. It is these limitations that place the claims beyond the reach of the ruling of *In re Thuau*. In other words, *In re Thuau* is not dispositive here, because the patentability of the claims does not rest upon a mere new use of an old composition, but rests upon a new and nonobvious composition.

In the case of *Schering Corp. v. Geneva Pharmaceuticals, Inc.*, 339 F.3d 1373 (Fed. Cir. 2003), the Court of Appeals for the Federal Circuit discussed the patentability of claims to a metabolite DCL in light of a prior art patent disclosing the drug loratadine. Evidence showed that there was no express disclosure of DCL and no mention of the metabolites of loratadine in the prior patent, yet DCL was necessarily formed as a metabolite by carrying out the process disclosed in the earlier '233 patent. After holding that the inherent result of administering loratadine to a patient is the formation of DCL, the Court went further to provide guidance to Applicants for properly claiming inventions when "bare compound claims" are unpatentable.

The Court advised that:

> A skilled patent drafter, however, might fashion a claim to cover the metabolite in a way that avoids anticipation. For example, the metabolite may be claimed in its pure and isolated form, as in Kratz and Bergstrom, or as a pharmaceutical composition (e.g., with a pharmaceutically acceptable carrier). ... The '233 patent would not provide an enabling disclosure to anticipate such claims because, for instance, the '233 patent does not disclose isolation of DCL.
> *Schering Corp. v. Geneva Pharmaceuticals, Inc.*, 339 F.3d 1373, 1381 (Fed. Cir. 2003)

Applicant asserts that its present claims are drafted consistent with the foregoing advice of the Federal Circuit, because independent claim 26 is not directed to bare dipercarboxylic acids, but to a combination of components in a measured amount and substantially free from other organic compounds. Applicant is not claiming an old composition as dealt with by *In re Thuau*, but instead is claiming a combination of components including an exothermic control agent. The Schepers and Coope patents do not suggest any need for an exothermic control agent as in the presently claimed composition. Reconsideration and withdrawal of the rejection is requested.

Schepers does not disclose a solid particulate composition, but rather discloses a non-aqueous liquid composition of dipercarboxylic acids that have low solubility in the non-aqueous liquid. The

dipercarboxylic acids disclosed by Schepers are mono- or di-percarboxylic amido or imido acids. (Schepers, col. 8, ln. 43-45). These compounds are high molecular weight compounds and Schepers does not disclose their solubility in water. However, because of their high molecular weight, these compounds disclosed by Schepers would not be considered to be soluble in water at concentrations high enough to form a sterilizing solution. This low water-solubility is confirmed by Coope, the secondary reference. (Coope, col. 5, ln., 46-50).

Applicant claims, *inter alia,* dipercarboxylic acids that may be stored as a solid at room temperature and that are soluble in water to form an aqueous solution having a concentration of at least 0.1 wt. %. (claim 26). The 0.1 wt % concentration is a concentration that is high enough to form a sterilizing solution.

Schepers does not disclose, teach, suggest or motivate that the high molecular weight peracid compounds that are discussed therein may be dissolved in water at a concentration of at least 0.1 wt. %. Schepers discloses solubility of various compounds in non-aqueous solutions, but not in aqueous solutions as claimed by Applicant. (Schepers, col. 12 – col. 14). Schepers discloses peroxyacid concentrations of between 0.1 to 10%, but these concentrations are not in an aqueous solution. Rather, the peroxyacids are "substantially insoluble" (Schepers, col. 3, line 57) in the non-aqueous liquid composition of the Scheper's invention. (Schepers, col. 4, ln. 30-31). Therefore, Schepers does not teach, suggest or motivate that there exists dipercarboxylic acids that are a stable solid and that can be solubilized in water to form a sterilizing solution as claimed by Applicant.

To establish a *prima facie* case of non-obviousness, there must be (1) some suggestion or motivation, either in the references themselves or in the knowledge generally available to one having ordinary skill in the art, to modify or to combine reference teachings; (2) a reasonable expectation of success; and (3) all the limitations of the claimed invention disclosed. See MPEP, § 2143.

Schepers does not teach, suggest, motivate or disclose that a dipercarboxylic acid may be stored as a solid and then solubilized in water to form a sterilizing solution having a concentration of at least 0.1 %. In fact, the acids disclosed by Schepers are all high molecular weight acids that are not soluble in water at high enough concentrations to achieve a 0.1 % concentration as claimed by Applicant. Therefore, Schepers does not present *a prima facie* case of obviousness against Applicant's claimed invention. Reconsideration and withdrawal of the rejection is respectfully requested.

Coope discloses the same high molecular weight acid types as Schepers. Coope specifically states that the acids disclosed therein are not soluble in water. Coope states, "When in liquid form, the surfactants serve not only to clean but importantly function as a structuring system to suspend the water-insoluble amido peroxyacids in water or any other solvent carrier." (Coope, col. 5, ln., 46-50). Since the acids disclosed by Coope are not water soluble, Coope does not disclose, teach or suggest a dipercarboxylic acid that is soluble in water at concentrations sufficient to form a sterilizing solution as claimed by Applicant. (claim 26).

Because neither Coope nor Schepers disclose, teach, or suggest a dipercarboxylic acid that is soluble in water at sterilizing concentrations, a *prima facie* case of obviousness has not been presented. Indeed, both Coope and Schepers disclose high molecular weight acids that are not soluble in water, as stated by Coope.

Applicant believes that the Examiner must give full consideration to the functional limitations of the claim when determining obviousness. Functional limitations should be given patentable weight when the function limitations are nonobvious over the prior art. See In re Mills, 916 F.2d 680 (Fed. Cir. 1990). Here, claim 26 includes the limitation of "one or more dipercarboxylic acids that are solid at room temperature and soluble at sterilizing concentrations in water." The compounds of this limitation are limited by their chemical class, i.e., dipercarboxylic acids, and are further limited to only those dipercarboxylic acids that function to form a "solid at room temperature" and that are "soluble at sterilizing concentrations in water." These functional limitations are neither disclosed nor suggested by Schepers or Coope. Reconsideration and withdrawal of the rejection is requested.

Attention is drawn to claim 31, which claims only a certain six C5 to C9 dipercarboxylic acids and combinations thereof. By contrast, Schepers says that "[t]he peroxyacids used in the compositions of the invention are amide or imide peroxyacids . . ." (Schepers, col. 3, lines 8-9). Coope discloses "a new series of amido-type peroxycarboxylic acids." (Coope, col. 2, lines 43-44). Applicant asserts that there is no disclosure of the claimed C5-C9 dipercarboxylic acids, and that there is no suggestion to modify the teaching of Schepers or Coope to use these acids. An indication of the allowability of claim 31 is requested.

Claims 26-37, 40-42 and 44-49 stand rejected under 35 U.S.C 103(a) over U.S. Patent No.

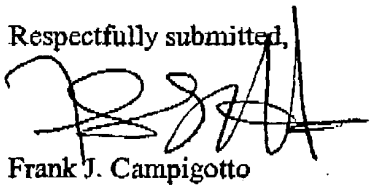
5,437,868 (Oakes, *et al.*) and U.S. Patent No. 5,049,298 (Ploumen, *et al.*). Oakes has disclosed using a liquid dipercarboxylic acid as an antimicrobial agent. Oakes, using the information known to those having ordinary skill in the art, does not teach or disclose that a SOLID dipercarboxylic acid may be dissolved to form an aqueous solution that is a sanitizing solution, as Applicant claims.

On the other hand, Ploumen discloses solid dipercarboxylic acids that are *not soluble* in water. Ploumen states "The invention relates to a process for the preparation of bleaching granules containing a solid, *water-insoluble* peroxy acid and a hydratable inorganic material. (Ploumen, Abstract, emphasis added). Therefore, neither Ploumen nor Oakes describes, teaches or suggests that a diperacid may be stored as a solid and then dissolved to form sterilizing aqueous solution as claimed by Applicant.

Because neither of the cited references teaches nor suggests each and every limitation claimed by Applicant, Applicant respectfully asserts that a prima facie case of obviousness has not been presented. Reconsideration and withdrawal of the rejection is respectfully asserted.

In conclusion, Applicant submits that all remaining claims in the present application are entitled to allowance and such action is earnestly solicited. In the event there are additional charges in connection with the filing of this Response, the Commissioner is hereby authorized to charge the Deposit Account No. 50-0714/LYNN/0120.A of the firm of the below-signed attorney in the amount of any necessary fee.

Respectfully submitted,



Frank J. Campigotto
Attorney for Applicant
Registration No. 48,130
STREETS & STEELE
13831 Northwest Freeway, Suite 355
Houston, Texas 77040
(713) 939-9444

Customer No. 24945